THE WEINBERG GROUP INC.

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April 1, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

COURIER 04/01/04

Withdrawal of Dosage Strengths in Citizen Petition
Docket Number 02P-0406/CP1

Dear Sir or Madam:

Pursuant to 21 CFR §10.30(g), the undersigned hereby withdraws, without prejudice to resubmission, certain dosage strengths specified in the following petition:

- Petition to request the Food and Drug Administration to declare that Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension 200 mg/28.5 mg, 400 mg/57 mg, and 600 mg/42.9 mg are suitable for submission as an abbreviated new drug application (dated September 10, 2002, submitted by Nicholas M. Fleischer, R.Ph., Ph.D., Vice President, Clinical Pharmacology & Biopharmaceutics, THE WEINBERG GROUP INC.)

The original petition was received by the Dockets Management Branch on 09/10/02 and was assigned docket number 02P-0406/CP 1.

We respectfully request that this Petition be amended to withdraw two of the strengths from the petition, with the third strength remaining. Specifically, the 200 mg/28.5 mg and 400 mg/57 mg Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension strengths should be withdrawn, leaving the 600 mg/42.9 mg dosage form of Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension as the sole subject of the Petition.

02P-0406 WDL 1

We are withdrawing the two strengths from this petition at the request of the Agency to change the reference listed drug, and we are resubmitting those strengths as a new Suitability Petition. We understand that the committee has completed deliberations on the original petition (02P-0406/CP1) and we have been requested to change the reference listed drug. We have complied with this request.

The Pediatric Waiver Request, dated March 10, 2004 and submitted by Nicholas M. Fleischer, R.Ph., Ph.D., Vice President, Clinical Pharmacology & Biopharmaceutics, THE WEINBERG GROUP INC., will apply to the 600 mg/42.9 mg dosage form of Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension.

Sincerely,

Nicholas Fleischer kh

Nicholas M. Fleischer, R.Ph., Ph.D.
Vice President
Clinical Pharmacology & Biopharmaceutics
THE WEINBERG GROUP INC.

NMF/kh

cc Gary Buehler, Director, Office of Generic Drugs